DELIVERY SYSTEM USING BALLOON CATHETER

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FIELD OF THE INVENTION

This invention concerns a novel delivery system using a balloon catheter. The preferred embodiment of the invention is a novel method for placing embolic coils within an aneurysm.

BACKGROUND OF THE INVENTION

The use of embolic coils placed within an aneurysm for treating the aneurysm is well known. Various devices are known for delivering the embolic coils through the patient's vessel to the aneurysm. Typically these embolic coils, which generally take the form of helically wound coils or random wound coils, are coupled to a coil deployment device which serves to introduce the coils into the aneurysm and then enables release of the coils through various types of release mechanisms. It has been found to be difficult to place the coils in the exact position desired because of the relative lack of stability of the deployment device within the vessel during the introduction of the embolic coil to the aneurysm.

It is, therefore, an object of the invention to provide a method for placing embolic coils in a relatively precise manner, with appropriate stability.

Another object of the present invention is to provide a system for placing embolic coils within an aneurysm, which system is relatively simple for the physician to operate.

A further object of the present invention is to provide a method for delivering

guidewires, embolics, diagnostic, and therapeutic agents via a delivery lumen in a relatively simple, efficient and stable manner.

A still further object is to provide a delivery catheter that enables the delivery of embolic coils within an aneurysm in a relatively simple, stable and effective manner.

Another object of the present invention is to provide a delivery catheter that can be utilized to deliver guidewires, embolics, diagnostic, and therapeutic agents via a delivery lumen.

A further object of the present invention is to provide a delivery catheter that is relatively simple in construction and easy to manufacture.

Other objects of the present invention will become apparent as the description proceeds.

SUMMARY OF THE INVENTION

In accordance with the present invention, a novel method is provided for placing a medical agent at a location to be treated within the vessel of a patient. The method comprises the steps of providing a catheter having a proximal end and a distal end, a balloon adjacent to the distal end, and an inflation port at the proximal end communicating via an inflation lumen with a balloon. A guidewire opening is provided at the distal end and a spaced, side opening is provided adjacent to the distal end. The catheter is introduced into the vessel of a patient via a guidewire which extends through the guidewire opening to generally align the side opening with the location to be treated. The balloon is inflated to stabilize the position of the catheter. A medical agent is thereafter introduced from the proximal end of the catheter and through the side opening to deliver the medical agent to

the location within the patient=s vessel to be treated. Thereafter, the balloon is deflated and the catheter is withdrawn from the patient=s vessel.

In accordance with an illustrative embodiment of the present invention, a novel method is provided for placing an embolic coil at a location within an aneurysm. The method comprises the steps of providing a catheter having a proximal end and a distal end, a balloon adjacent to the distal end, an inflation port at the proximal end communicating via an inflation lumen with the balloon, a guidewire opening at the distal end and a spaced, side opening adjacent the distal end. The catheter is introduced into the vessel of a patient via a guidewire extending through the guidewire opening to generally align the side opening with the aneurysm. The balloon is inflated to stabilize the position of the catheter and an embolic coil deployment device is introduced to the proximal end of the catheter through the side opening via a delivery lumen to delivery an embolic coil into the aneurysm. Once the desired number of embolic coils are delivered into the aneurysm, the balloon is deflated and the catheter is thereafter withdrawn from the patient=s vessel.

In the illustrative embodiment, a delivery port is provided at the proximal end communicating with the delivery lumen. The guidewire opening at the distal end also communicates with the delivery lumen.

In the illustrative embodiment, the catheter is preloaded with a guidewire extending from the delivery port through the delivery lumen and distal of the guidewire opening.

In the illustrative embodiment, a balloon catheter is provided. The balloon catheter comprises a catheter body having a proximal end and a distal end. A balloon is located adjacent to distal end and an inflation port is located at the proximal end. The catheter

body defines an inflation lumen with the inflation port communicating via the inflation lumen with the balloon. A delivery port is provided at the proximal end of the catheter. The catheter body defines a delivery lumen that is separate from the inflation lumen. A guidewire opening is provided at the distal end communicating with a delivery lumen. A side opening is provided adjacent to the distal end, spaced from the guidewire opening, and communicating with a delivery lumen. The balloon is radially aligned with the side opening and is oppositely positioned on the catheter with respect to the side opening.

In one embodiment of the invention, the guidewire opening and the side opening both communicate with the delivery lumen. In another embodiment of the invention, the guidewire opening communicates with a guidewire lumen and the side opening communicates with a separate delivery lumen.

In accordance with one embodiment of the invention, a hydraulic deployment system is utilized for delivering an embolic coil, via a catheter, to an aneurysm. The hydraulic deployment device includes a positioning catheter having a distal tip for retaining an embolic coil. When the positioning catheter is pressurized with a fluid, the distal tip expands outwardly to release the coil at the preselected position within the aneurysm.

A more detailed explanation of the invention is provided in the following description and claims, and is illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partial sectional view of a delivery catheter constructed in accordance with the principles of the present invention;

Fig. 2 is a partial sectional view of a vascular occlusive coil deployment system that

can be used with the catheter of Fig. 1;

Fig. 3 is a diagrammatic view the delivery catheter of Fig. 1 in use to deliver an embolic coil to an aneurysm;

Fig. 4 is a cross-sectional view of the catheter of Fig. 3, taken along the plane of the line 4-4' of Fig. 3;

Fig. 5 is a cross-sectional view of the catheter of Fig. 3, taken along the plane of the line 5-5' of Fig. 3;

Fig. 6 is a cross-sectional view of the catheter of Fig. 3, taken along the plane of the line 6-6' of Fig. 3;

Figs. 7-10 are diagrammatic sequential views of a method of placing embolic coils in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

Referring to Figs. 1 and 3-6, a balloon catheter 10 is illustrated therein. Balloon catheter 10 includes a tubular catheter body 12 having a proximal end 14 and a distal end 16. At the proximal end 14 there is an inflation port 18 and a delivery port 20. A flexible balloon 22 is located adjacent distal end 16 and is in fluid communication with an inflation lumen 24, which is in fluid communication with inflation port 18. A secondary port (not shown) may also be carried by the catheter and may be in fluid communication with inflation lumen 24. The secondary port, and inflation lumen 24 could be used to purge air trapped in the balloon and body.

The catheter body and balloon are preferably formed of one or more polymers, as is well known in the art. As an example although no limitation is intended, the proximal

portion of the catheter may be formed from nylon and the remainder of the catheter to its distal end may be formed of polyurethane. The inflatable balloon 22 may be formed from silicone material although it is to be understood that various other balloon materials and other materials for forming a catheter may be used as is known in the art of balloon catheters.

Catheter body 12 also defines a delivery lumen 26 which communicates with delivery port 20. Catheter body 12 also has a side opening 28 which is oppositely and radially aligned with balloon 22 and is in communication with delivery lumen 26.

Also in communication with delivery lumen 26 is a guidewire opening 30 which opening 30 is axially aligned with the catheter body 12 and is generally perpendicular to side opening 28.

Fig. 5 shows a cross-section of balloon 22 when it is fully inflated; Fig. 6 shows, as reference numeral 22', the balloon with a reduced diameter and as indicated by reference numeral 22'=, the original inner diameter of the balloon.

In Fig. 2, there is illustrated a deployment device 40 for embolic coils. It is to be understood that the device illustrated in Fig. 2 for deploying embolic coils is an example of numerous deployment devices which may be used with the present invention and reference is made to Hieshima U.S. Patent No. 6,113,622, issued September 5, 2000, the disclosure of which is incorporated herein, for more details of the structure and operation of the embolic coil deployment device of Fig. 2.

Although a preferred embodiment of the invention concerns the deployment of embolic coils, it is to be understood that the invention can be used for the deployment of other medical agents, including liquid embolic agents, biocompatible polymer-solvent

combinations, biocompatible polymers, and other embolizing compositions as are known in the art. Further, the medical agent that is deployed could be a diagnostic agent or a therapeutic agent. Although it will be apparent from the description how other medical agents may be deployed pursuant to the present invention, since an embolic coil is a preferred embodiment the description of the invention will be primarily referenced to the deployment of embolic coils.

The deployment device 40 of Fig. 2 includes a syringe 42, coupled to the proximal end of a catheter 44. An embolic coil 46 is disposed within the lumen of the distal end 48 of the catheter. The proximal end of the coil 46 is tightly held within the lumen of the distal section 48 of catheter 44 until the deployment system is activated for release of the coil. Syringe 42 includes a threaded piston 50 which is controlled by handle 52 for infusing fluid into the interior of the catheter 44. Catheter 44 includes a winged hub 54 which aids in the insertion of the catheter into the delivery port 20 of catheter 10.

Embolic coil 46 may take various forms and configurations. Its proximal end is within distal end 48 of catheter 44, which distal end 48 is flexible to form a fluid type seal with the proximal end of coil 46. When a hydraulic pressure is applied by piston 50 to the interior of catheter 44, the distal section 48 begins to expand radially to release coil 46 from the distal end 44 and to deploy coil 46 at the desired location, for example within an aneurysm.

It is to be understood that various types of deployment devices may be used including but not limited to those operating electrically, mechanically, adhesively, magnetically, etc. and coil 46 may take numerous forms as is well know in the art.

In accordance with the present invention, catheter 10 is utilized to enable the stable

delivery of embolic coils to an aneurysm. Fig. 3 is a diagrammatic view of catheter 10 enabling the delivery of a coil 46 to a brain aneurysm 60 through side port 28 of the catheter 10. The method for placing the embolic coil 46 at a location within aneurysm 60 is illustrated, in sequence, in Figs. 7-10.

Referring to Fig. 7, catheter 10, which has previously been preloaded with a guidewire 62, is introduced into the patient=s vessel 64. Guidewire 62 is preloaded to extend through delivery port 20, delivery lumen 26 and guidewire opening 30. The distal end of guidewire 62 is fed through a vessel, followed by catheter 10 containing guidewire 62, so that opening 28 will be aligned adjacent the aneurysm 60. Once so aligned, as illustrated in Fig. 8, balloon 22 will be inflated by providing inflation fluid via inflation lumen 24 to balloon 22 with the outer tip 22a of balloon 22 being compressed against the inner wall 64a of the vessel 64. This will serve to stabilize the catheter 10 and maintain its location within the vessel.

Once catheter 10 is in position with side opening 28 aligned with the aneurysm 60 and the balloon 22 compressed against the vessel wall, guidewire 62 is withdrawn via delivery port 20 and a catheter such as catheter 44, connected at its proximal end to a deployment device such as device 40, is inserted via delivery port 20 into delivery lumen 26. When the embolic coil 46 reaches side port 28, it will exit side port 28 into the aneurysm 60. When the coil has been placed in the desired location with the aneurysm, the coil is then released from the deployment device and the deployment device is withdrawn via the delivery port 20.

While balloon 22 remains compressed against the vessel wall, another embolic coil may be attached to the catheter 44 of the delivery device 40. The catheter 44 of the

delivery device 10 is again inserted into the delivery port 20 and through the delivery lumen 26 to side port 28 so that another embolic coil will be placed in a desired location within aneurysm 60. This process can be repeated until a desired number of coils have been placed within the aneurysm. The balloon 22 is then deflated and catheter 10 is removed from the vessel.

It can be seen that a novel system has been disclosed in which an embolic coil is securely placed within an aneurysm with a catheter that is stabilized and is relatively simple in construction and easy to use. Although an illustrative embodiment of the invention has been shown and described, it is to be understood that various modifications and substitutions may be made by those skilled in the art without departing from the novel spirit and scope of the present invention. For example, as stated above an additional port could be used in communication with the balloon to purge air trapped in the balloon and body. Instead of a single lumen used for both the guidewire and the embolic coil delivery device, a guidewire lumen which communicates with the guidewire opening at the distal end and a separate delivery lumen which communicates with the side opening could be utilized. Further, in addition to the delivery of embolics, the system can be utilized to delivery guidewires, diagnostics and therapeutic agents via a delivery lumen. The multiple lumen body may be composed of polymers and/or metals and a balloon may be preformed and attached to the inflation lumen adjacent the distal end of the catheter or formed from the inflation lumen of the multiple lumen body. Other modifications may be made which fall within the scope of the following claims.